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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
RANGREJ, SHEETAL	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/787,045
Filing Date: February 25, 2004
Appellant(s): HATLESTAD et al.

Michael P. Horvath
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 08/25/2010 appealing from the Office action mailed 04/07/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are pending, rejected, and appealed in the application:

1-11, 13, 14, and 16-28.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except

for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,824,512	Warkentin, et al.	11-2004
2004/0147969	Mann, et al.	07-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim1-6, 8-10, 13-14, 16-22 and 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Warkentin et al. (U.S. Patent No. 6,824,512).

1. As per claim1, Warkentin teaches a medication storage, therapy, and consumption management system, comprising:

-an implantable device configured to implantably electrically monitor fluid retention **(Warkentin: col. 10, 66, to col. 11, 12)**;

-an external, non-ambulatory pill-dispensing containment unit configured to accessibly house diuretic medication, the containment unit including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication **(Warkentin: figures 4A-4C)**;

-a health management host system coupled to the containment unit in a manner that allows data transmission **(Warkentin: col. 12, 21-38)**;

-said containment unit including communications and control system that records and transmits data relating to a medication event, the medication event data including information related to the dispensing, said containment unit control system further providing for transmitting and receiving medication therapy data **(Warkentin: col. 10, 44-65)**;

-said health management host system configured to receive data related to the medication event, receive physiologic data, analyze the patient physiologic data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data **(Warkentin: col. 10, 66, to col. 11, 12)**.

2. As per claim 2, the system of claim 1 is as described. Warkentin further teaches wherein the patient physiological data comprises weight, fluid retention data, data monitored by an implantable device and neuro-hormonal data **(Warkentin: col. 10, 66, to col. 11, 12)**.

3. As per claim 3, the system of claim 1 is as described. Warkentin further teaches wherein the containment unit is further configured to communicate wirelessly with said health management host system **(Warkentin: col. 6, 63 to col. 7, 6)**.

4. As per claim 4, the system of claim 1 is as described. Warkentin further teaches wherein the containment unit is configured with a display device to illustrate a medication therapy strategy **(Warkentin: col. 9, 19-63)**.

5. As per claim 5, the system of claim 4 is as described. Warkentin further teaches wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system **(Warkentin: col. 12, 21-38)**.

6. As per claim 6, the system of claim 1 is as described. Warkentin further teaches wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein **(Warkentin: 10, 44-65)**.

7. As per claim 8, the system of claim 1 is as described. Warkentin further teaches wherein said health management host system processes said data related to the medication event data and said patient physiological data, and in response thereto provides for the generation of an updated medication therapy regimen **(Warkentin: col. 10, 66, to col. 11, 12)**.

8. As per claim 9, Warkentin teaches an electronic patient health management system, comprising:

-an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data **(Warkentin: col. 10, 66, to col. 11, 12)**;

-an external, non-ambulatory, pill dispensing a medication therapy management device configured to accessibly house diuretic medication, the medication therapy management device including a diuretic medication pill receptacle configured to house the diuretic medication and configured to be selectively accessed by a person to dispense the diuretic medication, the medication therapy management device being configure to store medication event data related to at least one of dispensing or patient consumption of medication, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the medication event data **(Warkentin: figures 4A-4C; col. 10, 44-65)**; and

-a patient wellness host system, communicatively coupled to the medication therapy management diagnostic device, configured to receive the processed data and use the processed data to generate a diuretic medication therapy regimen **(Warkentin: col. 12, 21-38)**.

9. As per claim 10, the system of claim 9 is as described. Warkentin further teaches wherein the medication therapy management diagnostic device is further configured to provide a reminder to a patient when it is time to take the medication **(Warkentin: 10, 44-65)**.

10. As per claim 13, the system of claim 9 is as described. Warkentin further teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via an Internet connection **(Warkentin: col. 12, 21-38)**.

11. As per claim 14, the system of claim 9 is as described. Warkentin further teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to

the patient wellness host system via a wireless communication link **(Warkentin: col. 6, 63 to col. 7, 6)**.

12. As per claim 16, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device **(Warkentin: col. 10, 66, to col. 11, 12)**.

13. As per claim 17, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises weight data **(Warkentin: col. 10, 66, to col. 11, 12)**.

14. As per claim 18, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data **(Warkentin: col. 10, 66, to col. 11, 12)**.

15. As per claim 19, the system of claim 9 is as described. Warkentin further teaches wherein data related to the at least one patient physiological health factor comprises renal function data **(Warkentin: col. 10, 66, to col. 11, 12)**.

16. As per claim 20, the system of claim 9 is as described. Warkentin further teaches wherein the patient wellness host system is configured to process said data received in order to develop a therapeutic response **(Warkentin: col. 10, 66, to col. 11, 12)**.

17. As per claim 21, the system of claim 20 is as described. Warkentin further teaches wherein the developed therapeutic response comprises revising medication regime, maintaining current medication regime, and recommending a diet plan **(Warkentin: col. 10, 66, to col. 11, 12)**.

18. As per claim 22, the system of claim 9 is as described. Warkentin further teaches wherein the patient wellness host system is a computer, which comprises with a memory, a processor and a user interface **(Warkentin: col. 9, 2-18)**.

19. Claims 24-27 recite substantially similar limitations as those already addressed in claims 1-8, and, as such, are rejected for similar reasons as given above.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 7, 11, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warkentin et al. (U.S. Patent No. 6,824,512) in view of Mann et al. (U.S. Publication No. 2004/0147969).

22. As per claim 7, the system of claim 1 is as described. Warkentin does not explicitly teach wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level.

Mann, however, further teaches wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level **(Mann: para. 373)**.

One of ordinary skill in the art would have recognized that applying the known technique of Mann would have yielded predictable results and resulted in an improved system. It would

have been recognized that applying the technique of Warkentin to the teachings of Mann would have yielded predictable results because the level of ordinary skill in the art demonstrated by the references applied shows the ability to incorporate such data processing features into similar systems.

23. As per claim 11, the system of claim 9 is as described. Warkentin does not explicitly teach comprising an external medical measurement device for measuring data related to at least one patient physiological health factor **(Mann: para. 19; 23)**.

Mann, however further teaches comprising an external medical measurement device for measuring data related to at least one patient physiological health factor **(Mann: para. 19; 23)**.

The motivation to combine the teachings is the same as claim 7.

24. As per claim 23, the system of claim 9 is as described. Warkentin does not explicitly teach wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level.

Mann, however, teaches wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level **(Mann: para. 349)**.

The motivation to combine the teachings is the same as claim 7.

25. Claim 28 recite substantially similar limitations as those already addressed in claim 11, and, as such, are rejected for similar reasons as given above.

(10) Response to Argument

1. Warkentin establishes each and every element recited or incorporated into the claims.

Appellant's argument	Claim language	Prior art citation	Examiner's interpretation
Warkentin fails to establish an implantable device to electrically monitor fluid retention. Appellant states that Warkentin merely refers to a system for use in a neural stimulation or cardiac rhythm and therapy context--not in a fluid monitoring treatment context.	"an implantable device configured to implantably electrically monitor fluid retention"	"implantable medical devices chronically monitor physiologic parameters of the patient"	Examiner interprets monitoring of fluid retention to be one of the many physiologic parameters of the patient; therefore since Warkentin's implantable device monitors physiologic parameters, it is therefore monitoring fluid retention. As one skilled in the art, fluid retention is a term of the art that is measured by measuring fluid retention in the body, which Warkentin teaches.
Warkentin fails to teach a pill dispensing containment unit configured to accessibly house diuretic medication.	"pill-dispensing containment unit configured to accessibly house diuretic medication"	"The structure includes pill containers that protrude upwards from the surface for pill or drug containment."	Examiner states that Warkentin teaches a pill container that houses medication.
Warkentin fails to teach generating a diuretic medication therapy regimen using the analysis of the patient's physiological data and the medication event. Appellant argues that there is no description in Warkentin to use its system for generating a diuretic medication therapy regimen using the analysis.	"receive data related to the medication event, receive patient physiological data including fluid retention data collected by the implantable device, analyze the patient physiological data and the medication event data, and generate a diuretic medication therapy regimen using the analysis"	"IMDs may be programmed to monitor the efficacy of the drug monitoring the physiological effects of the drug on the patient" "Use of various communications media between the remote web-based expert data center and the programmer to remotely exchange clinically significant information and ultimately effect real-time drug intake and prescriptive changes" (col. 4, 42-47)	Examiner states that Warkentin teaches gathering information regarding administration of the pill and monitoring the physiologic parameters to generate an analysis of the two events related to generate a trend curve; therefore providing a report on the effects of the medication in relation to the physiological parameters.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Sheetal R. Rangrej/
Examiner, Art Unit 3686

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686

Conferees:

Gerald J. O'Connor /GJOC/
Supervisory Patent Examiner
Group Art Unit 3686

Vincent Millin/vm/

Appeals Conference Specialist